ORIGINAL

U.S. Department of Justice
Drug Enforcement Administration

Office of the Administrator *Springfield, VA 22152*

May 2, 2018

IN THE MATTER OF

Morris & Dickson Co., LLC
10301 Highway 1 South
Shreveport, Louisiana 71115

Morris & Dickson Co., LLC
d/b/a Spark Drug, Inc.
336 Saint George Avenue
Jefferson, Louisiana 70121

ORDER TO SHOW CAUSE AND
IMMEDIATE SUSPENSION OF REGISTRATION

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

NOTICE is hereby given to inform you of the immediate suspension of Drug Enforcement Administration ("DEA") Certificates of Registration Nos. RM0314790 and RM0335732, pursuant to 21 U.S.C. § 824(d), because your continued registrations constitute an imminent danger to the public health and safety. Notice is also given to afford you an opportunity to show cause before the DEA in Arlington, Virginia, or a location designated by the Administrative Law Judge, on July 9, 2018, (if you request such a hearing), as to why the DEA should not revoke your registrations pursuant to 21 U.S.C. § 824(a)(4) and deny any pending applications for renewal or modification of such registrations or for additional DEA registrations, because your continued registrations are inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(b).

As detailed below, this order states the DEA's basis for this Order to Show Cause and Immediate Suspension of Registration, including a ***non-exhaustive summary*** of facts and law at issue as well as citations to laws and regulations that you have violated (*see* 21 C.F.R. §§ 1301.36(e) and 1301.37(c), which DEA construes *in pari materia*). In order to preserve your rights in this proceeding, you must appear in these revocation proceedings by filing a notice of appearance or request for hearing in the manner prescribed by regulations within 30 days from the receipt of this Order.

1. Opioids can play an important role in pain management. However, when opioids are prescribed, dispensed, or distributed outside of lawful channels, the risk that they will be abused is substantial. The risks of opioid abuse are both myriad and significant, and include the possibility of overdose and death. In 2016 alone, Arkansas, Georgia, Louisiana, Mississippi, Missouri, Oklahoma, and Tennessee suffered over 4,100 opioid-related deaths.[1] Deaths that are part of a nationwide problem that caused the acting Secretary of the Department of Health and Human Services to declare, in October 2017, that the "opioid crisis" was a "public health emergency."[2] The diversion of prescription opioids has played a material role in that crisis and while DEA seeks to prevent such diversion, "this Agency cannot do it all itself. It must rely on registrants to fulfill their obligation under the [Controlled Substances] Act to ensure that they do not supply controlled substances to entities which act as pushers." *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487 (2007).

2. Morris & Dickson Co., LLC ("M&D") is a distributor of opioid medications, including oxycodone and hydrocodone, to pharmacies located in a number of states, including *inter alia* the seven states referenced above. Between January 2014 and September 2017, M&D shipped over 221,000,000 dosage units of hydrocodone and over 157,000,000 dosage units of oxycodone to customers located those seven states. As explained in greater detail below, M&D failed to maintain effective controls against diversion in a myriad of ways, including failing to report to DEA thousands of unusually large orders for hydrocodone and oxycodone, and shipping those orders without dispelling red flags consistent with diversion. M&D's failures to uphold its obligations as a DEA registrant are significant, widespread, and ongoing, and create an imminent danger to public health or safety within the meaning of 21 U.S.C. § 824(d). *See infra*, ¶¶ 98-101.

3. M&D is currently registered with the DEA as a distributor in Schedules II through V under DEA Certificate of Registration No. RM0314790 at 10301 Highway 1 South, Shreveport, Louisiana 71115. This Certificate of Registration expires by its own terms on January 1, 2019.

4. M&D, d/b/a Spark Drug, Inc., is currently registered with the DEA as a distributor in Schedules II through V under DEA Certificate of Registration No. RM0335132 at 336 Saint George Avenue, Jefferson, Louisiana 70121. This Certificate of Registration expires by its own terms on January 1, 2019.

5. M&D is currently licensed with the Louisiana Board of Drug and Device Distributors under License No. 4299 at 10301 Highway 1 South, Shreveport, Louisiana 71115. This license expires by its own terms on December 31, 2018.

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[1] National Institute on Drug Abuse, "Opioid Summaries by State," *available at* https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state.

[2] https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html

6. M&D, d/b/a Spark Drug, Inc., is currently licensed with the Louisiana Board of Drug and Device Distributors under License No. 2015 at 336 Saint George Avenue, Jefferson, Louisiana 70121. This license expires by its own terms on December 31, 2018.

Relevant Legal Standards

7. A drug distributor may not maintain its DEA Certificate of Registration if it "has committed such acts as would render [its] registration . . . inconsistent with the public interest" as defined in Section 823 of the Controlled Substances Act. 21 U.S.C. § 824(a)(4). In order for its registration to be in the public interest, a drug distributor is required to, *inter alia*, "maintain[] effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. § 823(b)(1); *see also* 21 C.F.R. § 1301.71 (a distributor "shall provide effective controls and procedures to guard against theft and diversion of controlled substances."); *Masters Pharmaceutical, Inc.*, 80 Fed. Reg. 55,418 (2015), *pet. for review denied Masters Pharmaceuticals, Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017); *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487 (2007).

8. Additionally, registrants "shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b); *see also Masters Pharmaceutical, Inc.*, 80 Fed. Reg. 55,418 (2015), *pet. for review denied Masters Pharmaceuticals, Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017); *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487 (2007).

9. Under Louisiana law, a drug distributor must "establish, maintain, and adhere to written policies and procedures" including "a procedure . . . to review excessive or suspicious purchases." La. Admin. Code tit. 46, Pt. XCI, § 313.

10. DEA's investigation of M&D's distribution practices and policies revealed that M&D failed to "maintain[] effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels" in violation of 21 U.S.C. §§ 823(b)(1) and failed to adequately "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and report them to DEA, in violation of 21 C.F.R. § 1301.74(b). Specifically, and as explained herein, M&D consistently ignored and/or failed to implement its due diligence and suspicious order monitoring policies and failed to conduct meaningful due diligence into these orders to ensure that the controlled substances were not diverted into other than legitimate channels. Instead, M&D has routinely shipped—***and, at least as recently as February 28, 2018, continues to ship***—controlled substances despite evidence suggesting a likelihood of diversion.

Failure to Operate an Effective System to Disclose "Suspicious Orders"

11. During a DEA investigation into the dispensing practices of certain pharmacies, DEA investigators became aware of the fact that M&D was supplying many of the top purchasing pharmacies in a number of states with oxycodone and hydrocodone. It was determined during DEA's investigation that M&D's pharmacy customers routinely purchase hydrocodone and oxycodone in quantities substantially in excess of the average purchases by pharmacies in the same zip code, state, or nationally. For example, DEA identified at least six pharmacies in the State of Louisiana which purchased between seven and thirteen times the state average of oxycodone from M&D. Similarly, DEA identified nine pharmacies in four other states which purchased more than five times the respective state average of oxycodone from M&D.

12. During a routine on-site DEA audit of M&D in 2017, DEA investigators orally requested copies of any suspicious order reports filed by M&D between 2015 and 2017. M&D provided DEA with copies of two suspicious order reports.

13. Concerned by the low number of suspicious order reports that M&D provided in response to the request noted above, DEA conducted a search of its own files and identified a total of three suspicious order reports (including the two mentioned above) filed by M&D between January 2014 and September 2017. In two of these instances (for reports dated April 2017), M&D shipped the order for controlled substances prior to reporting the order to DEA. With respect to the third report (dated April 2014), the report did not provide sufficient information for DEA to determine whether or not M&D shipped the order for controlled substances.

14. In a still-further effort to evaluate M&D's due diligence efforts, DEA on February 5, 2018, served an administrative subpoena on M&D seeking records "pertaining to suspicious order reports filed by [M&D] for controlled substances or records and documents pertaining to due diligence or internal investigations conducted on possible suspicious orders made for controlled substances from January 1, 2016 to present."

15. By response received on or about February 23, 2018, M&D indicated that it employs a "four-fold" approach to detect suspicious orders. M&D stated that its suspicious order monitoring/detection system consists of—or was being modified to include—the following safeguards:

    a. First, M&D has engaged a third-party vendor to analyze the dispensing practices of its customers. Reports are requested before M&D accepts a new customer and on an annual basis thereafter. If the third-party vendor identifies a pharmacy as suspicious, reports are requested more frequently.

    b. Second, M&D's Compliance Officer conducts a monthly market basket analysis on M&D's customers to analyze the ratio of controlled to non-controlled substances being purchased by the customer.[3]

[3] Neither M&D's response nor its written policies identify the ratio it views as suspicious. *Cf. Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. at 36,492 (noting that in a typical pharmacy, "controlled substances might

c. Third, M&D purports to be in the process of implementing computerized order monitoring software to identify orders that are more than 10 times the 90 day rolling average of orders for that particular controlled substance from that particular customer.

d. Fourth, M&D relies on its warehouse employees to identify deviations from customer ordering patterns.

16. M&D's response to DEA's subpoena indicated that it did not believe that it was required to maintain records on investigations conducted into potentially suspicious orders. In pertinent part, M&D stated in its response that "formal records are not kept in the regular course of business on the investigation of orders which do not result in the finding of a 'suspicious order'" under DEA regulations. And, in fact, no such records were produced in response to DEA's subpoena.

17. The records that M&D produced confirmed that between January 2014 and September 2017, M&D reported three "suspicious orders" to DEA pursuant to 21 C.F.R. § 1301.74(b). In each case, M&D shipped the order for controlled substances to the customer notwithstanding its conclusion that the order was "suspicious."

18. DEA conducted a statistical analysis of orders for oxycodone and hydrocodone placed with M&D between January 2014 and September 2017, to identify extremely large individual pharmacy transactions and extremely large monthly pharmacy volume totals using a standard statistical method for identifying improbable events. DEA's purpose in doing so was to identify and eliminate orders that, when evaluated by their size, could conceivably have been regarded by M&D as being of a usual size, relative to that customer's historical ordering quantities. The remaining orders are, by definition, "unusual," from the standpoint of generally accepted statistical analysis, and thus should have been identified as potentially "suspicious" within the meaning of 21 C.F.R. § 1301.74(b).

19. DEA's analysis identified ***16,596*** unusually large orders of oxycodone (totaling approximately ***18,600,000*** dosage units). DEA's analysis identified ***6,382*** unusually large orders of hydrocodone (totaling approximately ***27,200,000*** dosage units).

20. Nevertheless, M&D filled and shipped each of these orders and did not report any of these orders as suspicious to DEA, except as noted above.

21. As a result, M&D has failed to maintain effective controls against the diversion of controlled substances into other than legitimate channels, in violation of 21 U.S.C. §§ 823(b)(1) and (e)(1) and 21 C.F.R. § 1301.71. M&D has further failed to identify and report suspicious orders to DEA, in violation of 21 C.F.R. § 1301.74(b).

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amount to between five and twenty percent of the pharmacy's purchases with the other eighty to ninety percent of its purchases being non-controlled drugs"); *accord Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. at 55,477.

22. In fact, M&D has routinely shipped—and, at least as recently as February 28, 2018, continues to ship—controlled substances to customers without conducting adequate due diligence and despite the fact that those customers have been identified by M&D's third-party vendor as raising red flags consistent with diversion; have been identified by M&D's own employees as suspicious; and have placed orders identified by DEA's statistical analysis as being of unusually large relative to historical ordering quantities. 21 C.F.R. § 1301.74(b).

23. Indeed, despite being aware of information suggesting that controlled substances that M&D shipped to certain customers were being diverted, M&D failed to perform a reasonable follow-up investigation into these red flags (let alone an investigation that was able to dispel these concerns), continued to fill these orders, and did not report them to DEA.

24. As set forth below with respect to a representative sample of M&D's pharmacy customers, M&D consistently ignored and/or failed to implement its due diligence and suspicious order monitoring policies identified in Paragraph 15. According to DEA's records, M&D has been the predominant supplier of oxycodone and hydrocodone in 2018 for the five sample pharmacies that remain M&D customers. M&D failed to conduct—or failed to document the resolution of—meaningful due diligence into orders placed by these pharmacies to ensure that the controlled substances were not diverted into other than legitimate channels.

Failure to Report Suspicious Orders from Wallace Drug Company Inc.

25. Wallace Drug Company Inc. d/b/a Wallace Discount Drugs ("Wallace") is registered with the DEA as a retail pharmacy under DEA Certificate of Registration No. FW6006363 with a registered address of 520 North Magnolia Street, Laurel, Mississippi 39440.

26. The third-party "Initial Risk Evaluation Report" prepared on or about September 2017, and requested by M&D, identified Wallace as dispensing a higher quantity of both hydrocodone and oxycodone tablets than the national average and engaging in cash transactions for controlled substances at a higher percentage than the national average.

27. Despite the red flags identified by M&D's third-party vendor, and despite M&D's purported policies identified above, *see supra* ¶ 15, M&D did not conduct any additional due diligence on Wallace.

28. According to M&D records provided to DEA, an M&D employee noted on January 9, 2018, with respect to Wallace: "Might need to check on this guy he has ordered 12 bottles of 1,000 hydrocodone/apap 10/325 item 51627 the last two days and has another order in today for 12 more, so 36 bottles of 1,000 in three days. Also got 12 of the 5mg 1,000 and 24 of the 7.5mg 1,000.....***so looks like he is hitting this stuff hard***!" (emphasis added).

29. Despite the concerns raised by an M&D employee, and despite M&D's purported policies identified above, *see supra* ¶ 15, M&D did not conduct any additional due diligence on Wallace or report any orders by Wallace to DEA.

30. Between October 2017 and March 2018, M&D shipped 91 orders of hydrocodone (totaling 196,660 dosage units) and 201 orders of oxycodone (totaling 113,100 dosage units) to Wallace.

31. In fact, according to data reported by M&D to DEA, M&D shipped orders for controlled substances to Wallace throughout the First Quarter of 2018, and at least as recently as February 28, 2018.

32. Despite being aware of the red flags identified by M&D's third-party vendor and despite observations made by an M&D employee indicating that Wallace was ordering an unusual quantity of controlled substances, M&D failed to conduct adequate due diligence sufficient to resolve concerns over the unusual nature of the above orders, continued to ship controlled substances to Wallace, and failed to report any orders to DEA.

Failure to Report Suspicious Orders from Bordelon's Super-Save Pharmacy

33. Bordelon's Super-Save Pharmacy ("Bordelon's") is registered with the DEA as a retail pharmacy under DEA Certificate of Registration No. AB6203549 with a registered address of 6920 Plank Road, Baton Rouge, Louisiana 70811.

34. The third-party "Initial Risk Evaluation Report" prepared on or about May 2017, and requested by M&D identified, Bordelon's as dispensing a higher quantity of both hydrocodone and oxycodone tablets than the national average.

35. Despite the red flags identified by M&D's third-party vendor and presented to M&D on or about May 2017, and despite M&D's purported policies identified above, *see supra* ¶ 15, M&D did not conduct any additional due diligence on Bordelon's.

36. Between January 2014 and September 2017, M&D shipped 359 orders of hydrocodone (totaling 430,570 dosage units) and 1,184 orders of oxycodone (totaling 458,430 dosage units) to Bordelon's.

37. Using the statistical analysis described above, *see supra* ¶ 18, DEA identified 33 unusually large orders of oxycodone (totaling 52,700 dosage units) shipped by M&D to Bordelon's between March 2014 and June 2017 and seven unusually large orders of hydrocodone (totaling 54,000 dosage units) shipped by M&D to Bordelon's between September 2014 and December 2014. These unusually large orders included, *inter alia*:

    a. An order for 2000 dosage units of oxycodone shipped in January 2017, (approximately ***ten times*** the median order for Bordelon's).

    b. An order for 3,000 dosage units of oxycodone shipped in May 2015, (approximately ***fifteen times*** the median order for Bordelon's).

c. Four orders for hydrocodone (totaling 42,000 dosage units) shipped in September 2014, (approximately ***forty-two times*** the median orders for Bordelon's).

38. M&D's due diligence files presented to DEA do not indicate that it resolved the red flags noted above. Accordingly, M&D failed to conduct adequate due diligence sufficient to resolve concerns over the unusual nature of the above orders.

39. Notwithstanding the above, M&D shipped all orders placed by Bordelon's and did not report any of these orders to DEA.

40. According to data reported by M&D to DEA, M&D shipped orders for controlled substances to Bordelon's throughout the First Quarter of 2018 and at least as recently as February 28, 2018.

Failure to Report Suspicious Orders from Folse Pharmacy

41. Folse Pharmacy ("Folse") is registered with the DEA as a retail pharmacy under DEA Certificate of Registration No. BF0636451 with a registered address of 4000 Fourth Street, Marrero, Louisiana 70072.

42. The third-party "Initial Risk Evaluation Report" prepared on or about December 2013, and requested by M&D, classified Folse as "***high risk***" (emphasis in original) and noted that a higher percentage than average of the prescriptions filled by Folse were for controlled substances, that hydrocodone represented a high percentage of the prescriptions that were filled, and that a higher percentage than average of the controlled substances prescriptions were paid for in cash. The third-party vendor continued to flag these same concerns for M&D in its reports as recently as August 2017.

43. The market basket analysis, *see supra* ¶ 15.b, prepared with respect to January 2016, indicated that 51% of Folse's total purchase volume consisted of controlled substances. The market basket analysis prepared for December 2017, indicated that 42% of Folse's total purchase volume consisted of controlled substances.

44. Despite the red flags identified by M&D's third-party vendor as well as the market basket analysis, and despite M&D's purported policies identified above, *see supra* ¶ 15, M&D did not conduct any additional due diligence on Folse.

45. Between January 2014 and September 2017, M&D shipped 973 orders of hydrocodone (totaling 1,586,630 dosage units) and 2314 orders of oxycodone (totaling 2,270,700 dosage units) to Folse.

46. Using the statistical analysis described previously, *see supra* ¶ 18, DEA identified 89 unusually large orders of oxycodone (totaling 417,000 dosage units) shipped by M&D to Folse between January 2014 and September 2017. DEA further identified 83 unusually large orders of hydrocodone (totaling 706,000 dosage units) shipped by M&D

to Folse between January 2014 and September 2017. These unusually large orders included, *inter alia*:

a. Two orders for 6,000 dosage units (12,000 total) of oxycodone shipped in September 2017, (each order approximately ***twelve times*** the median order for Folse).

b. Two orders for 12,000 dosage units (24,000 total) of hydrocodone shipped in August 2017, (each order approximately ***twelve times*** the median order for Folse).

c. Two orders for 7,000 dosage units (14,000 total) of oxycodone shipped in September 2015, (each order approximately ***fourteen times*** the median order for Folse).

47. M&D failed to conduct adequate due diligence sufficient to resolve concerns over the unusual nature of the above orders.

48. Notwithstanding the above, M&D shipped all orders placed by Folse and did not report any of these orders to DEA.

49. According to data reported by M&D to DEA, M&D shipped orders for controlled substances to Folse throughout the First Quarter of 2018, and at least as recently as February 28, 2018.

Failure to Report Suspicious Orders from Pharmacy Specialties Group Inc.

50. Pharmacy Specialties Group Inc. ("Pharmacy Specialties") is registered with the DEA as a retail pharmacy under DEA Certificate of Registration No. FP4243589 with a registered address of 12110 Highway 71 South, Fort Smith, Arkansas 72916.

51. The third-party "Initial Risk Evaluation Report" prepared on or about May 2016, and requested by M&D, noted that a higher percentage than average of the prescriptions filled by Pharmacy Specialties were for controlled substances and that a higher percentage than average of the controlled substances prescriptions were paid for in cash.

52. Despite the red flags identified by M&D's third-party vendor, and despite M&D's purported policies identified above, *see supra* ¶ 15, M&D did not conduct any additional due diligence on Pharmacy Specialties.

53. Between January 2014 and September 2017, M&D shipped 184 orders of hydrocodone (totaling 224,330 dosage units) and 464 orders of oxycodone (totaling 238,520 dosage units) to Pharmacy Specialties.

54. Using the statistical analysis described previously, *see supra* ¶ 18, DEA identified 7 unusually large orders of oxycodone (totaling 16,800 dosage units) shipped by M&D to Pharmacy Specialties between November 2015 and October 2016. DEA further identified five unusually large orders of hydrocodone (totaling 38,000 dosage units)

shipped by M&D to Pharmacy Specialties between September 2015 and August 2016. These unusually large orders included, *inter alia*:

a. An order for 2,400 dosage units of oxycodone shipped in October 2016, (approximately ***five*** times the median order to Pharmacy Specialties).

b. An order for 12,000 dosage units of hydrocodone shipped in January 2016, (approximately ***twelve times*** the median order to Pharmacy Specialties).

c. An order for 12,000 dosage units of hydrocodone shipped in September 2015 (approximately ***twelve times*** the median order to Pharmacy Specialties).

55. M&D failed to conduct adequate due diligence sufficient to resolve concerns over the unusual nature of the above orders.

56. According to M&D records provided to DEA, an M&D employee noted on March 7, 2017, with respect to Pharmacy Specialties: "Check out this guys [*sic*] usage for item 74458, compared to his overall warehouse purchasing, this seems quite elevated to me .....???? Also seemingly buying a lot of other CII merchandise."

57. On December 13, 2017, an M&D employee commented with respect to Pharmacy Specialties: "Henry will give the customer a warning about his Oxy purchases. Too much cash, too much growth. Will re-run & if no improvement will either restrict or cut off completely."

58. Despite the concerns raised by M&D's employees, and despite M&D's purported policies identified above, *see supra* ¶ 15, M&D did not conduct any additional due diligence on Pharmacy Specialties or report any orders to DEA. Furthermore, M&D did not "restrict or cut off" Pharmacy Specialties.

59. Notwithstanding the above, M&D shipped all orders placed by Pharmacy Specialties and did not report any of these orders to DEA.

60. According to data reported by M&D to DEA, M&D shipped orders for controlled substances to Pharmacy Specialties throughout the First Quarter of 2018, and at least as recently as February 28, 2018.

Failure to Report Suspicious Orders from Dave's Pharmacy

61. Dave's Pharmacy ("Dave's") is registered with the DEA as a retail pharmacy under DEA Certificate of Registration No. BD5662386 with a registered address of 1220 Barataria Blvd., Marrero, Louisiana 70072.

62. The third-party "Initial Risk Evaluation Report" prepared on or about April 2014 and requested by M&D identified Dave's as presenting a "relatively high risk" to M&D (emphasis in original). Specifically, the report noted that Dave's dispensed a "significantly high" quantity of hydrocodone and had "high cash payments" for

controlled substances. The third-party vendor continued to flag similar concerns in its reports to M&D as recently as August 2017.

63. Despite the red flags identified by M&D's third-party vendor, and despite M&D's purported policies identified above, *see supra* ¶ 15, M&D did not conduct any additional due diligence on Dave's.

64. Between January 2014 and September 2017, M&D shipped 1,990 orders of hydrocodone (totaling 3,273,280 dosage units) and 4,808 orders of oxycodone (totaling 2,029,400 dosage units) to Dave's.

65. Using the statistical analysis described previously, *see supra* ¶ 18, DEA identified 94 unusually large orders of oxycodone (totaling 241,900 dosage units) shipped by M&D to Dave's between December 2014 and August 2017. DEA further identified seven unusually large orders of hydrocodone (totaling 84,000 dosage units) shipped by M&D to Dave's between March 2015 and October 2016. These unusually large orders included, *inter alia*:

    a. An order for 6,000 dosage units of oxycodone shipped in April 2017, (approximately ***twenty times*** the median order of Dave's).

    b. Three orders for 6,000 dosage units (18,000 dosage units total) of oxycodone placed in June 2015, (each order approximately ***twenty times*** the median order of Dave's).

    c. Two orders for 12,000 dosage units (24,000 dosage units total) of hydrocodone shipped in March 2015, (each order approximately ***twelve times*** the median order of Dave's).

66. M&D failed to conduct adequate due diligence sufficient to resolve concerns over the unusual nature of the above orders.

67. Notwithstanding the above, M&D shipped all orders placed by Dave's for hydrocodone and oxycodone for this time period and did not report any of these orders to DEA.

Failure to Report Suspicious Orders from Hephzibah Pharmacy LLC

68. Hephzibah Pharmacy LLC ("Hephzibah") is registered with the DEA as a retail pharmacy under DEA Certificate of Registration No. AV5145695 with a registered address of 4819 Windsor Spring Road, Hephzibah, Georgia 30815.

69. The third-party "Initial Risk Evaluation Report" prepared on or about March 2017, and requested by M&D, with respect to Hephzibah noted that a higher than average percentage of the prescriptions filled by Hephzibah were for controlled substances; Hephzibah was dispensing large quantities of oxycodone and hydrocodone; and a large percentage of the controlled substances were being paid for in cash.

70. Despite the red flags identified by M&D's third-party vendor, and despite M&D's purported policies identified above, *see supra* ¶ 12, M&D did not conduct any additional due diligence on Hephzibah.

71. Between April 2017 and June 2017, M&D shipped 57 orders of hydrocodone (totaling 21,800 dosage units) and 92 orders of oxycodone (totaling 18,620 dosage units) to Hephzibah.

72. According to M&D records provided to DEA, on March 17, 2017, an M&D employee indicated that M&D would maintain an account for Hephzibah "with the understanding of the customer that they must work on clearing up issues that Pro Compliance found, high cash, trinity & high quantities on hydrocodone & oxycodone."

73. Despite the concerns raised by an M&D employee, and despite M&D's purported policies identified above, *see supra* ¶ 15, M&D did not conduct any additional due diligence on Hephzibah or report any orders to DEA.

74. Using the statistical analysis described previously, *see supra* ¶ 18, DEA identified 16 unusually large orders of oxycodone (totaling 8,000 dosage units) shipped by M&D to Hephzibah between April 2017 and May 2017. These unusually large orders included:

    a. Eight orders for oxycodone (totaling 4,000 dosage units) shipped in May 2017, (each order approximately ***five times*** the median order by Hephzibah).

    b. Eight orders for oxycodone (totaling 4,000 dosage units) shipped in April 2017, (each order approximately ***five times*** the median order by Hephzibah).

75. M&D failed to conduct adequate due diligence sufficient to resolve concerns over the unusual nature of the above orders.

76. In December 2017, DEA investigators requested information regarding any customer accounts that were terminated by M&D "due to suspicious ordering or through [M&D's] due diligence."

77. In December 2017, M&D included Hephzibah on a list of customer accounts closed by M&D "due to our due diligence efforts" effective June 20, 2017, but further stated that M&D "did not find [this] account to exhibit suspicious activity or excessive orders."

78. Notwithstanding the above, M&D shipped all orders placed by Hephzibah and did not report any of these orders to DEA.

Failure to Report Suspicious Orders from The Wellness Pharmacy, Inc.

79. The Wellness Pharmacy, Inc. ("Wellness") was registered with the DEA as a retail pharmacy under DEA Certificate of Registration No. BT7485166 with a registered address of 5801 Crossing Boulevard, Antioch, Tennessee 37013.

80. The third-party "Initial Risk Evaluation Report" prepared on or about December 2013, and requested by M&D, identified Wellness as dispensing "high quantities" of oxycodone and hydrocodone and noted that controlled substances accounted for a "significantly higher" percentage of total prescriptions filled than the national average. The third-party vendor continued to flag these issues for M&D as recently as November 2017.

81. The market basket analysis, *see supra* ¶ 15.b, prepared with respect to January 2016, indicated that 84% of Wellness' total purchase volume consisted of controlled substances. The market basket analysis prepared for December 2017, indicated that 92% of Wellness' total purchase volume consisted of controlled substances.

82. Despite the red flags identified by M&D's third-party vendor as well as the market basket analysis, and despite M&D's purported policies identified above, *see supra* ¶ 15, M&D did not conduct any additional due diligence on Wellness.

83. Between January 2014 and September 2017, M&D shipped 4,997 orders of oxycodone (totaling 3,083,080 dosage units) and 1,351 orders of hydrocodone (totaling 1,569,010 dosage units) to Wellness.

84. Using the statistical analysis described previously, *see supra* ¶ 18, DEA identified 113 unusually large orders of oxycodone (totaling 369,800 dosage units) shipped by M&D to Wellness in June 2014 and September 2017. DEA further identified 3 unusually large orders of hydrocodone (totaling 18,000 dosage units) shipped by M&D to Wellness between October 2014 and June 2015. These unusually large orders included, *inter alia*:

    a. An order for 6,000 dosage units of oxycodone shipped in June 2017, (approximately ***fifteen times*** the median order by Wellness).

    b. An order for 6,000 dosage units and an order for 5,000 dosage units (11,000 total) of oxycodone shipped in April 2017, (approximately ***15 times*** and ***12 times***, respectively, the median order by Wellness).

    c. Two orders for 6,000 dosage units (12,000 total) of hydrocodone shipped in October 2014, (each order approximately ***six times*** the median order by Wellness).

85. M&D failed to conduct adequate due diligence sufficient to resolve concerns over the unusual nature of the above orders.

86. By letter dated December 16, 2017, Wellness reported that it had gone out of business and retired its DEA Certificate of Registration.

87. M&D supplied Wellness with controlled substances until Wellness retired its DEA Certificate of Registration.

88. Notwithstanding the above, M&D shipped all orders placed by Wellness and did not report any of these orders to DEA.

Failure to Report Suspicious Orders from Wilkinson Family Pharmacy

89. Wilkinson Family Pharmacy ("Wilkinson") was registered with the DEA as a retail pharmacy under DEA Certificate of Registration No. FW3669198 with a registered address of 708 Wood Duck Lane, Slidell, Louisiana 70461.

90. The third-party "Initial Risk Evaluation Report" prepared on or about December 2013, and requested by M&D, identified Wilkinson as presenting a "significantly high risk" to M&D (emphasis in original). Specifically, the report noted that a "significantly higher" than average percentage of the prescriptions filled by Wilkinson were for controlled substances; Wilkinson was dispensing large quantities of oxycodone, hydrocodone, benzodiazepines, and carisoprodol; and a large percentage of the controlled substances were being paid for in cash. The third-party vendor continued to flag the quantity of oxycodone and hydrocodone dispensed and the ratio of controlled to non-controlled substances prescriptions filled in reports to M&D as recently as March 2017.

91. Despite the red flags identified by M&D's third-party vendor, and despite M&D's purported policies identified above, see supra ¶ 15, M&D did not conduct any additional due diligence on Wilkinson.

92. Between January 2014 and April 2017, M&D shipped 1,284 orders of hydrocodone (totaling 1,431,680 dosage units) and 4,564 orders of oxycodone (totaling 3,100,140 dosage units) to Wilkinson.

93. DEA's analysis identified 2 unusually large orders of oxycodone (totaling 11,000 dosage units) shipped by M&D to Wilkinson in May 2015 and April 2017. DEA's analysis identified 50 unusually large orders of hydrocodone (totaling 425,500 dosage units) shipped by M&D to Wilkinson between January 2014 and December 2015. These unusually large orders included, *inter alia*:

    a. An order for 6,000 dosage units of oxycodone shipped in April 2017, (approximately ***fifteen times*** the median order by Wilkinson).

    b. An order for 12,000 dosage units of hydrocodone shipped in September 2015, (approximately ***twelve times*** the median order by Wilkinson).

    c. Three orders for 12,000 dosage units of hydrocodone (totaling 36,000 dosage units) shipped in September 2014, (each order approximately ***twelve times*** the median order by Wilkinson).

94. On April 19, 2017, Wilkinson surrendered its DEA Certificate of Registration for cause following a DEA investigation into its dispensing practices.

95. M&D supplied Wilkinson with controlled substances until Wilkinson surrendered its DEA Certificate of Registration for cause.

96. M&D failed to conduct adequate due diligence sufficient to resolve concerns over the unusual nature of the above orders.

97. Notwithstanding the above, M&D shipped all orders placed by Wilkinson and did not report any of these orders to DEA.

Imminent Danger to Public Health or Safety

98. As detailed above, M&D failed to report to DEA over ***32,000*** unusually large orders of controlled substances, relative to that customer's historical ordering quantities—totaling approximately ***18,600,000*** dosage unites of oxycodone and ***27,200,000*** dosage units of hydrocodone—and failed to conduct adequate due diligence address or resolve indicia of suspiciousness, in violation of 21 C.F.R. § 1301.74(b).

99. Notwithstanding this failure to conduct adequate due diligence, M&D filled these orders and routinely shipped controlled substances to pharmacies despite evidence suggesting a substantial likelihood of diversion.

100. Moreover, in at least two of the three instances where M&D reported an order to DEA as "suspicious," M&D nevertheless filled the order and shipped the controlled substances notwithstanding its own conclusion that the order was suspicious and that M&D was not able to resolve its concerns over the likelihood of diversion.

101. Due to M&D's manifest failure to maintain effective controls against the diversion of controlled substances, including the shipping of controlled substances without performing adequate due diligence and the shipping of controlled substances despite significant evidence that its customers had exhibited red flags consistent with diversion, M&D's continued operation poses an "imminent threat to public health or safety" within the meaning of 21 U.S.C. § 824(d).

IN view of the foregoing, and pursuant to 21 U.S.C. §§ 823(b) and 824(a)(4), it is my preliminary finding that your continued registration is inconsistent with the public interest. It is my preliminary finding that you have failed to maintain effective controls against the diversion of controlled substances, including the shipping of controlled substances without performing adequate due diligence and the shipping of controlled substances despite significant evidence that your customers had exhibited red flags consistent with diversion. It is also my preliminary finding, significantly in light of the rampant and deadly problem of prescription controlled substance abuse, that your continued registrations during the pendency of these proceedings would constitute an imminent danger to the public health or safety because of the substantial likelihood that you will continue to unlawfully distribute controlled substances, thereby allowing the diversion of controlled substances unless your DEA CORs are suspended. Under the facts and circumstances described herein, it is my conclusion that your continued registration, while these proceedings are pending, constitutes an imminent danger to the public health and safety. *See* 21 U.S.C. § 824(d). Accordingly, pursuant to the provisions of 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36(e), and the authority granted me under 28 C.F.R. § 0.100, DEA Certificates of Registration RM0314790 and RM0335732 is hereby suspended, effective immediately. Such suspension shall remain in effect until a final determination is reached in these proceedings.

PURSUANT to 21 U.S.C. § 824(f) and 21 C.F.R. § 1301.36(f), the Special Agents and Diversion Investigators of the DEA who serve this Order to Show Cause and Immediate Suspension of Registration are authorized to place under seal or to remove for safekeeping all controlled substances that you possesses pursuant to the registrations, which I have herein suspended. The said Agents and Investigators are also directed to take into their possession your DEA Certificates of Registration RM0314790 and RM0335732 and any unused order forms.

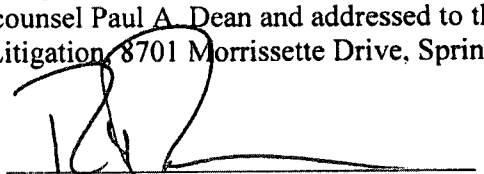
THE following procedures are available to you in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, you may file with the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. *See* 21 C.F.R. § 1301.43(a). If you fail to file such a request, the hearing shall be cancelled in accordance with paragraph 3, below.

2. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, you may file with the DEA a waiver of hearing together with a written statement regarding its respective positions on the matters of fact and law involved. *See* 21 C.F.R. § 1301.43(c).

3. Should you decline to file a request for a hearing or, should you request a hearing and then fail to appear at the designated hearing, you shall be deemed to have waived the right to a hearing and the DEA may cancel such hearing, and I may enter my final order in this matter without a hearing based upon the evidence presented to me. *See* 21 C.F.R. §§ 1301.43(d) and 1301.43(e).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152. Matters are deemed filed upon receipt by the Hearing Clerk. *See* 21 C.F.R. § 1316.45. A copy of the same shall also be served on Government counsel Paul A. Dean and addressed to the Office of Chief Counsel, Diversion and Regulatory Litigation, 8701 Morrissette Drive, Springfield, VA 22152.



Robert W. Patterson
Acting Administrator
Drug Enforcement Administration

cc: Hearing Clerk, Office of Administrative Law Judges
Paul A. Dean, Counsel for the Government
John E. Beerbower, Counsel for the Government